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THE HUMAN GENOME PROJECT, DNA SCIENCE AND THE LAW: THE AMERICAN LEGAL SYSTEM'S RESPONSE TO BREAKTHROUGHS IN GENETIC SCIENCE

PANEL ONE: INTELLECTUAL PROPERTY AND GENETIC SCIENCE: THE LEGAL DILEMMAS

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P R O C E E D I N G S

PROFESSOR SARNOFF: Good morning. Welcome. Thank you all for coming. Let me reiterate Dean Pike's statement. We are truly blessed with a tremendously distinguished panel this morning, which I will introduce shortly. After the introduction, I will say just a few short remarks to orient you in the field and then I will turn it over to the panelists for about ten minutes of discussion each. This will be followed by an opportunity for them to respond to each other, after which we will take any questions you may have.

The first of our distinguished panelists is Todd Dickinson. Mr. Dickinson is a partner and co-chair of Howrey & Simon's Intellectual Property Practice. He has more than twenty-five years of experience in all aspects of intellectual property law and public policy, including patents, trademarks, copyrights, and trade secrets—the relationships between these areas we may hear about today.

Mr. Dickinson leads the firm's Intellectual Property Group's counseling, licensing, prosecution, strategic portfolio management, and government relations practice. Before joining Howrey, as many of you may know, Mr. Dickinson was Undersecretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office ("PTO").

At the PTO, Mr. Dickinson was the principal policy advisor to the President of the United States on intellectual property matters, and he was responsible for international intellectual property policy issues on behalf of the government.

To the right of Mr. Dickinson is John Kilyk. Mr. Kilyk has practiced intellectual property law at Leydig, Voit & Mayer for nearly twenty years. For the past five years he has held the position of Chairman of the Management Committee within the firm, which specializes in the practice of all aspects of intellectual property law.

Mr. Kilyk practices exclusively in the field of patent law, including patent litigation and prosecution, with a specific concentration in the areas of biotechnology and chemistry. Mr. Kilyk has extensive experience in formulating patent strategies and in managing patent portfolios, as well as in counseling and rendering opinions on patent validity, patent infringement, technology licensing, and the protection of trade secrets and other proprietary information.

To the left of Mr. Kilyk is Arti Rai. Professor Rai is an Assistant Professor of Law at the University of Pennsylvania. She has taught

classes covering, and has scholarly interests in, law and biotechnology, patent law, and health care regulation. Before joining the University of Pennsylvania, Professor Rai taught at the University of San Diego Law School and the University of Chicago Law School. She graduated from Harvard College, attended Harvard Medical School, and received her law degree from Harvard Law School, so she is Harvard through and through. After law school, she clerked for Judge Marilyn Patel in the Northern District of California.

Professor Rai has been a litigation associate at the Washington, D.C. office of Jenner & Block, an attorney at the Federal Programs Branch of the Department of Justice, and, before entering law teaching, Professor Rai was a Faculty Fellow at Harvard University's program on Ethics & Professions. She's authored numerous articles in this area, which are really tremendous, including articles on biotechnology, articles on patent law, and articles on health care regulation. She also is a co-author of *Law and the Mental Health System: Civil and Criminal Aspects*. In addition, she serves on the Board of Editors at the American Journal of Law and Medicine.

To my right, your left, of Professor Rai is Jack Spiegel. He is the Director of the Division of Technology, Development, and Transfer in the Office of Technology Transfer at the National Institutes of Health ("NIH"). Dr. Spiegel is the director of the Patent and Licensing Division of the Office of Technology Transfer in that particular division at NIH. He's been at the Office of Technology Transfer since 1990, where he has served as a patent advisor.

Dr. Spiegel came to NIH from the Patent and Trademark Office, where he served as a biotechnology patent examiner. Prior to his career in intellectual property, Dr. Spiegel was an assistant professor of biology at Catholic University. His research interests include in vitro models of cell interaction and involving embryonic nervous tissue. Dr. Spiegel received his Ph.D. in developmental biology and his postdoctoral training in neural anatomy at the University of Chicago.

Let me very briefly say just a few things. Patents provide a monopoly for the patent holder to keep other people from making, using, selling, or doing some other things with the inventions that they claim.[1] It's very important, therefore, to understand how much of a monopoly is given to the patent holder and in exchange for what.

What we have seen, particularly in the public debate over

1. *See* 35 U.S.C. § 271 (1982).

electronic commerce and business method patents, is the driving down of the amount of disclosed use, as well as the utility of what is disclosed. At the same time, we have seen the expansion of the claims to cover more and more basic elements or ways of doing things. You end up with a monopoly on an incredibly broad scope of activities in exchange for disclosing relatively simple uses and with relatively little investment of inventive effort.

That same phenomena is what's happening in biotechnology and is at the core of the Human Genome Project debate. What happens is that you now may be able to get a patent on basic pieces of biochemistry—for example, expressed sequence tags ("EST")[2]—and for a very limited disclosed utility you get the right to prevent others from making, using, and selling these tags in any particular form, not just for the utility that you disclose—which may be something as simple as a hybridization probe.[3]

That driving down of the scope—the utility of what you disclosed—but claiming a right to all sorts of broader utilities was discussed as early as 1853 in the seminal patent case of *O'Reilly v. Morse*.[4] Let me briefly read to you.

> No-one, we suppose will maintain that Fulton could have taken out a patent for his invention of propelling vessels by steam, describing the process and machinery he used, and claimed under it the exclusive right to use the motive power of steam, however developed, for the purpose of propelling vessels. It can hardly be supposed that under such a patent he could have prevented the use of the improved machinery which science has since introduced; although the motive power is steam, and the result is the propulsion of vessels. Neither could the man who first discovered that steam might, by a proper arrangement of machinery, be used as a motive power to grind corn or spin cotton, claim the right to

2. *See* Molly A. Holman & Stephen R. Munzer, *Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags*, 85 IOWA L. REV. 735 (2000) (characterizing expressed sequence tags (ESTs) "tiny fragments of genes"). "[A]n EST is generally about 400 to 500 nucleotides in length and encodes about 130 amino acids, whereas full-length genes are generally between 2000 and 25,000 nucleotides (including 5' and 3' noncoding regions)." *Id.* at 749.

3. A hybridization probe is where

> [o]ne strand of the DNA double helix is used to bind to a target strand of DNA. If the base sequences are complementary (i.e. adenine matches with thymidine, guanine with cytosine), then the two strands will form a double helix. If they are not complementary, then no helix will form. Thus, the DNA probe can be used as a reagent to detect when a specific DNA sequence is present among a mixture of sequences.

WILLIAM BAINS, BIOTECHNOLOGY FROM A TO Z 108-09 (1993) (discussing a hybridization probe).

4. 56 U.S. 62 (1853).

> the exclusive use of steam as a motive power for the purpose of producing such effects.[5]

What the Court was saying in *Morse* is that by disclosing one utility you don't get the right to claim all forms of utility for the thing that you've disclosed. That has since changed. That is why we now have a debate over whether the patent monopoly itself is too big a grant of power in exchange for what has gone before it, i.e., the disclosure of only the limited use. That is why you get arguments such as those for a registration system rather than a patent system for the valuable invention that was disclosed to the public,[6] which also assures that the invention does not stay locked up as a trade secret.

On the other hand, it is also why you end up having a problem. You could disclose only a little bit and still lock up too much of a patent monopoly, so that other people will have to purchase from you. Or, you can keep that information to yourself and thereby damage future investment, future invention, and the progress of science[7]—which was the premise of the constitutional power for a patent.[8]

Given that background, I'd like to turn it over to the panel with two fundamental questions in my mind. They will have, no doubt, lots of other things to add. Those questions are: "Where have the patent system and scientific response been heading—have we been foreclosing too much invention or have the grants of the patent monopoly really stimulated the degree of invention that we wanted?"

Second, wherever that balance is, "how has the patent system been changing the norms of scientific collaboration and economic competition, is it doing so in good ways, and are those changing norms of science affecting the rest of our lives in good ways?" Mr. Dickinson.

MR. DICKINSON: Thank you very much Professor Sarnoff. That was quite an interesting and, in many ways, provocative start to a discussion that we're going to have.

First of all, let me thank American University and the Washington College of Law for having all of us here. This is a very timely and interesting program.

Just let me say, in my time at the PTO, no issue is probably more interesting, the questions more challenging and difficult than ones

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5. *Id.* at 113.
6. *See, e.g.*, Holman & Munzer, *supra* note 2.
7. *See* U.S. CONST. art. I, § 8, cl. 8 (stating that Congress has the power to promote the useful arts and the progress of science).
8. *See id.*

surrounding genomics intellectual property. They can be as broad as some of the ones you outlined in terms of whether genomic invention should be patentable in the first place as a matter of ethics, down to what I call "devil in the details" kinds of questions, such as the utility and written description guidelines,[9] which were rewritten and republished several years ago. These guide the examiners in the PTO in the very specific day-to-day work that they have to engage in such as deciding whether something is patentable or not.[10]

Mr. Sarnoff cited a case from 1853.[11] Let me cite a Supreme Court case from 1980, and that's the case of *Diamond v. Chakrabarty*.[12] In it, the Supreme Court said that anything engineered or made by the hand of man was patentable subject matter.[13] That was a case directed toward a genetically modified, I guess you'd say, colony of microbes that were used to alleviate petroleum oil spills, and the General Electric Company filed a patent application on it.[14]

The Supreme Court found that the colony of microbes was indeed patentable subject matter, even though it was a living organism—a microbe of bacterium.[15] Most observers would say this kick-started and has continued to this day to maintain the United States' lead at least in biotechnology research and the commercialization of biotechnology research.

We lead the world in that. I think most observers would agree with the fact that the patent system applies to those types of inventions as a key component of that. So I guess one potential answer to the question that was posed is whether this does indeed spur innovation as it has throughout its entire existence, that the law indeed has done that.

Back to sort of the original question, I noticed that one of the materials you handed out today was a very good article from the ABA

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9. *See* Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001), *available at* http://www.uspto.gov/web/offices/pac/utility/utility.htm [hereinafter *Utility Guidelines*] (updating the revised interim utility examination guidelines from January of 2000). These guidelines were published to help applicants file nonprovisional utility patent applications by discussing the requirements for filing and forms to be used. *Id. See also* Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1 "Written Description" Requirement, 64 Fed. Reg. 3425 (Dec. 21, 1999), *available at* http://www.uspto.gov/web/offices/pac/writtendesc.pdf.

10. *Id.*

11. *See* O'Reilly v. Morse, 56 U.S. 62 (1853).

12. 447 U.S. 303 (1980).

13. *Id.* at 310 (noting that the "handi-work of nature" is not patentable subject matter).

14. *Id.* at 305.

15. *Id.* at 310.

journal.[16] It starts out with a quote from when the famed scientist Jonas Salk was asked whether he planned to patent his polio vaccine and he reportedly answered, "How can you patent the sun?"[17]

I was asked this question on the day that we put up our new database on the internet at the PTO, and just as a test I went in and plugged in Jonas Salk's name, and interestingly enough there appeared a patent issued to him that day for an AIDS vaccine. So, apparently in the twenty to thirty years between polio and AIDS, Dr. Salk's position on the issue must have changed a little bit.

I think other questions arose from some of the issues Professor Sarnoff raised, so let me just touch on them briefly. First of all, the question of whether something is patentable and whether a gene sequence or a genomic invention is patentable or can be patentable; and the separate, related, but very distinct question of whether and how you gain access to that technology. How is it licensed? How is it made available and to whom and under what terms is it made available? Those are very important but distinct questions in a lot of ways, and often that second question either tries to inform or even tries to derive the former.

Let me start with the question of how gene sequences are patentable in the first place—because a lot of people have that basic threshold question and they have trouble getting past it. From the patent law standpoint, a gene sequence is treated almost like any other chemical, any other chemical composition.

Even though it is found in nature, as is said, what the patent is granted on is not the form that's found in nature, but, rather, for the isolated and purified form of that gene. The chemical composition of that gene or that gene fragment has never been known before, and the scientist who has made that discovery, has made that invention, and is entitled to it because they have isolated and purified it.

As Professor Sarnoff correctly points out, another requirement of the patent law is that there be a utility that is disclosed for it.[18] Let me just briefly refresh everybody's recollection about the four statutory requirements for patentability. First of all, under section 101 there has to be patentable subject matter.[19] The Supreme Court says that

16. *See* Margaret Graham Tebo, *The Big Gene Profit Machine*, A.B.A. J. ON BIOTECH. L. at 46 (Apr. 2001).

17. *Id.*

18. 35 U.S.C. § 101 (2000) (stating that anyone who invents, discovers, or improves a *useful* process, machine, manufacture, or composition of matter may receive a patent).

19. *Id.* (describing patentable subject matter as a process, machine, manufacture or composition of matter).

can be almost anything.[20] Secondly, it has to have some utility,[21] and we're going to talk probably a fair bit about utility this morning.

The third requirement is that it has to be new.[22] It has to be novel and never discovered before by anybody.[23] That gets to the question of whether or not you're the first person to describe the chemical composition of the gene sequence. Even if it is new, it can't be so incremental over what's gone before it that it's what's called obvious; it has to be nonobvious.[24]

And fourth, it's a function of the fact that one of the key reasons for the patent system in the first place is to give incentive to people to make their inventions public and not keep them secret.[25] You have to make a full and complete disclosure when you file your patent application.[26]

So, let's return to that question of utility. As was pointed out, and I think correctly so, utility—particularly in the chemical arts—has traditionally been a very low threshold. And, as recently as the last year or the year before last, the Court of Appeals for the Federal Circuit ("CAFC"), which sits here in D.C. and decides all appeals at the first instance of patent cases, in a case called *Juicy Whip v. Orange Bang*,[27] found that the continuing utility requirement was indeed very, very low.[28]

Juicy Whip concerned something not at all related to gene sequences. It concerned a juice dispensing machine and the question was whether if you misled—if an element of the claim was actually something that didn't contribute to the functionality of the invention but was merely to disguise or mask actually the real functionality—did that possess utility if that was the only point of novelty associated with the invention.[29]

The court said, yes, that was sufficient utility.[30] So, again, and in

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20. Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980) ("Anything under the sun that is made by man").

21. *See* 35 U.S.C. § 101.

22. *See* 35 U.S.C. § 102 (stating generally that a person is entitled to a patent unless the subject matter of the patent was already known or used by others).

23. *Id.*

24. *See* 35 U.S.C. § 103 (stating that a patent will not be granted if the difference between the subject matter to be patented and the prior art would have been obvious at the time the invention was made).

25. *See* U.S. CONST. art. 1, § 8, cl. 8 (securing an exclusive right for inventors in respect to their discoveries for a limited time).

26. *See* 35 U.S.C. §§ 111-112.

27. 185 F.3d 1364 (Fed. Cir. 1999).

28. *Id.* at 1366.

29. *Id.* at 1366-67.

30. *Id.* at 1367 ("The fact that one product can be altered to make it look like another is in itself a specific benefit sufficient to satisfy the statutory requirement of

clear language, the court said that the barrier of utility was very low. All you had to disclose was a use of some sort. Now, this links to the question in gene sequences because, as I think was suggested by the introduction, there's a lot of concern that people will get very basic patents on individual gene sequences, particularly human gene sequences. And, most of what we will, I assume, talk about today is human gene sequences.

My good friends at the NIH have, for example, made a decision not to file patent applications on human gene sequences or gene fragments, like ESTs. That doesn't stop them from filing on rice genes and mouse genes and other types of genes. But the question of whether or not this utility requirement should be sufficiently high as a function of trying to keep patents from issuing that are too broad is, I think, a real core issue. So, one of the questions that we dealt with in my time at the PTO was trying to see if we could get that utility requirement up as high as we possibly could, under the law, in order to meet some of those concerns, while at the same time not going any further than the CAFC or presumably the Supreme Court would let us go. So, we republished our utility guidelines that the examiners use when they examine patent applications in this area.[31]

We raised the bar so that now a three-part test has to be met: (1) the utility has to be specific; (2) it has to be substantial; and (3) it has to be credible.[32] Those definitions are on the website of the PTO at www.uspto.gov. If you log on there, you will see that there are page-long definitions of what each of those terms mean.[33]

And, in the real world it has to have a real world practical utility that's disclosed. I think that what the reality is, in terms of what the office has accomplished, particularly in the gene fragment area, the EST area—where a lot of the principal concern lies—is that you'll see that a lot of the earliest filed applications on ESTs where the utility was either not disclosed at all or where it was disclosed as something very, very broad—like a diagnostic tool or something else like that—were allowed.

Those applications will not now be allowed. There has to be a much more specific, substantial, and credible utility before you can get a patent application—before the patent can be issued.

Some still raise the question, "Oh, how can you do it in the first place because it's found in my body? How can you do that?" As I

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utility.").

31. *See Utility Guidelines*, *supra* note 9.

32. *Id.* (describing the three-part test).

33. *Id.*

mentioned, it has to be isolated and purified. We have issued patent applications for hundreds of years to chemicals that are found in nature. For example, many pharmaceuticals are found in plant material and then the active ingredient is isolated from it.

A classic example is penicillin. You may know the story. Alexander Flemming, the Scottish scientist went to his petri dish one day and found that some bacteria he was growing had moved back from something on that dish. He looked into the dish at what that substance was and found it was mold that had come into his dish and contaminated his dish. Then he took that mold, grew more of the mold—actually, it grows naturally; you can find it on oranges if you leave oranges around long enough—and he isolated penicillin from that mold.

Well, he got a patent on the penicillin. He isolated it and purified it from a naturally occurring source. Well, you say, "That's all well and good for mold but what about people? We're talking about people here, aren't we?" Well, when the first discoverers of human insulin isolated that from the human pancreas and found that it was the chemical that regulated sugar metabolism, we issued them a patent on human insulin as well. So, we have been at this a fairly long time, and it's a fairly routine thing, at least from the patent law perspective.

Now, I mentioned the other question that's involved here, and that's the question of access, the question of license. So, if we can get over the hurdle of patentability, and we get the patent issued, then we have the question of how can we make sure that the technology is widely available. The threat is often posed that, yes, the patent grant is very broad and very extensive and very strong, so how can we make sure that the technology becomes as widely available as possible.

What almost always tends to happen though, in the real world, is that those folks who come up with these kinds of inventions and the need and the desire to exploit them will very often, if not always, make them available for licensing. The genomics companies, for example, Celera and others that are out in Maryland, make their money not by being a pharmaceutical company (at least not yet), rather, they're an information company. They sell information, and they make their money by doing that, so they're very eager to license this technology.

There are other examples around where companies may be compromising this a little bit or seem like they're compromising it a little bit. I had the distinct and very interesting opportunity to be on *60 Minutes* on this topic. They had a couple of folks on the other side

who had genes—one to a disease called Canavan's disease and one to a breast cancer gene—where the theory was that they were being kept off the market.

The reality is that they were charging a royalty rate, which was fairly consistent with standard royalty rates in the industry. The breast cancer test, for example, cost $300; the royalty of that was about $12. The University of Pennsylvania took exception to that because they wanted to be able to provide it as well. The reality is that most of the time, if not all of the time, the licensing protocol for these kinds of inventions is one which makes them widely accessible.

One key question in this area, and one that I address when we're in the office, is if multiple companies get gene sequence patents and you're developing a therapy which requires access to all those gene sequence patterns, you have to go from company to company to company to company. This may indeed create a situation where it's too costly.

So, one of the issues that we looked into, and there was a White Paper also on the PTO website, is this question of patent pooling.[34] It's been used, for example, with M-peg technology. It's used in electronics a lot such as M-peg technology and high-definition television, where all of the players in the industry get together, pool their patents, and have a common licensing protocol so that anyone can gain access. The result of that paper, and I think rightly so, was a suggestion that patent pooling could be applicable in the biotechnology area, and I'd be an advocate for that.

I've also been a strong advocate for companies like Celera and others to say, "Don't kill the goose that lays the golden egg." Yes, you have a very strong right, but if you exercise that in ways that the public disagrees with, you have the opportunity for that hand to come back and be bitten. I think most of them have heard that message.

So, thank you for having me here. I appreciate it.

MR. KILYK: Good morning, everyone. I'm honored to have been invited to participate in this symposium regarding the legal system's response to genetic science breakthroughs.

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34. *See* Jeanne Clark, *Patent Pools: A Solution to the Problems of Access in Biotechnology Patents*, at 4 (Dec. 5, 2000) [hereinafter *PTO White Paper*] (defining patent pooling as "an agreement between two or more patent owners to license one or more of their patents to one another or third parties"), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/patpoolcover.html. This PTO white paper suggests that patent pooling may be a solution to the concerns that biotechnology patents will result in a lack of access to biotechnology for the research and development of commercial products and for further basic biological research. *See id.* at 1.

I've been practicing in the intellectual property field for about twenty years, and for nearly all of my professional career I've been with Leydig, Voit in Chicago where I head up our firm's biotech practice group. In recent years, my colleagues and I have advised clients on a number of patent issues in the biotech field that grab the attention of the press and the general public.

Some of those have been alluded to by Mr. Dickinson. There are differences, however, in how the issues are presented by the press and how the issues are presented by clients to private practitioners like myself. Yet, when issues are presented by the clients, it can still be enlightening to look at the general issues in patent law with regard to genetic breakthroughs.

Several general press articles have asked the question, "How is it that someone can patent something like genetic material that exists in nature?" Other articles carry headlines with questions, such as "Can a corporation legally patent you?" And yet other articles in the general press have inquired whether a patent can be used to block me from using my own DNA to determine if I have a certain disease.

Now, these issues, when they're framed in such a broad fashion, really have two aspects to them. One aspect is the patent law aspect, and that involves understanding what the patent laws allow and do not allow and then applying that understanding to some outstanding problem to arrive at an outcome.

The other aspect is what I'll term a political aspect, and that involves whether that arrived-at outcome is something desirable for society. Certainly, on a day-in, day-out basis, other patent attorneys and I advise clients as to the first aspect—the patent law aspect. Those clients are seeking advice on solving particular problems as to what they can and cannot do.

Our firm represents corporations, universities, individual inventors, and even governmental organizations such as the NIH, which has several representatives in the symposium today. As a result, our firm finds itself on both sides of many patent law issues. Now, we obtain patents for clients. We defend those patents for those clients in court. But we also seek to invalidate patents that pose issues for our clients. So, we really are on all sides, as you would expect most lawyers to be on most legal issues.

These activities pertain to the patent law aspect of the issues as framed by the press rather than the political aspect. And, how the clients come to our firm to seek advice, again, is more of the patent law aspect, not whether we should be allowed to do certain things under the law—in other words, whether that law should even be on

the books.

This is not to say that patent attorneys don't have opinions regarding what I call political aspects. I do think, however, that the patent law aspects and the political aspects need to be kept in mind in analyzing these broader issues, particularly in the way they're framed by the general press.

One advantage that private patent practitioners bring to this discussion is that by sharing our experiences with the application of the patent laws to particular situations, we can certainly help shed light, or some would say heat, on the political aspect of these issues. But in the end, that aspect really represents a balancing of societal interests.

While these issues are new, in the sense that they pertain to a relatively new technology, the issues certainly are not unique in the patent law field, and that's already been alluded to by Mr. Dickinson. Many of the same types of questions have been asked with respect to other technologies and groundbreaking inventions when they first appeared on the scene.

The legal principles that patent practitioners apply to these situations, and indeed that are being applied today to resolve at least the patent law aspect of the broader issues as framed by the press, are the same legal principals that, by and large, have been in place for quite a long time. Indeed, the general legal principles are substantially the same as the principles used by the founders of my firm in the late 1800s when they were advising clients on the then revolutionary breakthroughs in mechanics, electronics, and chemistry. Now, we're in the position of applying them to biotechnology.

One of the things I hope that we'll be able to accomplish on this panel this morning is a discussion of some of the issues raised by the general press with respect to the patenting of genetic materials. At that time, I can provide some insights on how these broad issues are framed or presented to patent attorneys by clients seeking legal guidance—an example being the question I just posed of how can someone patent something that exists in nature.

As Mr. Dickinson has already explained, no one does that. The patent laws prohibit that and have always prohibited that. As a patent practitioner, what we're faced with is someone coming into our offices who has just sequenced a gene that has never been sequenced before and who has an appreciation of a particular utility for that sequence—for example, that it can be used to treat a certain disease.

Now that corporation or individual is asking us for ways in which to

protect that discovery, and we'll inform them that they can't patent what exists in nature, but they can certainly patent other aspects of their discovery. For example, they can patent the isolated and purified form of that gene or a method of using that gene to treat that certain disease.

What we'll explore with that client are those other aspects that can be patented. And as has already been alluded to, the devil's in the details—what exactly is that invention; how is it going to be defined in the patent; and then the enforcement and possible licensing of those patent rights.

The other question, as I alluded to, is can a corporation legally patent you? Of course it cannot. But that's usually not the issue that a patent practitioner is confronted with. Typically, what will happen is a corporation or a university may have done research with some genetic material obtained from a patient, for example, while that patient was undergoing some therapeutic protocol in a hospital. What is faced by that corporation or university is the question of ownership. What rights does that patient have in any patent that's obtained on the invention that was based on his genetic material? Again, there may be a debate as to whether that patent should be allowed at all.

There may even be some questions, or certainly some people have proposed the idea, of whether the person should have rights automatically in that patent. But right now it gets down to standard contract issues. What understanding did that person in that corporation or university have when that material was obtained which the corporation worked with?

So, those are the types of issues that we as patent practitioners face, and certainly we can go through other specific examples to help shed light on both the patent law aspects and what I've termed the political aspects.

Thank you very much.

PROFESSOR RAI: Hi. I also want to thank all of the folks at the Washington College of Law who have really done a tremendous job of organizing this symposium. I'm very honored to be invited to participate.

We've been asked to talk about dilemmas raised by intellectual property rights in genetic science. Let me start by saying that's an incredibly broad topic. I hesitate even to make any general observations about it, but I do have three observations that I will make at the outset and then I'll elaborate on them as time permits.

First, as has been discussed by the previous speakers and as many of

you probably know, we've seen quite a gold rush with respect to patent applications on genes and various pieces of genes known as expressed sequence tags and single nucleotide polymorphisms ("SNPs").[35] I'll talk about all those terms in a minute.

But let me caution that genes are just the beginning of genetic science. In fact, the mapping of the genome brings to mind Winston Churchill's observation three years into World War II that, quote, "This is not the end. It is not even the beginning of the end. But it is, perhaps, the end of the beginning."[36] I think that's precisely what we have with respect to the mapping of the genome. We're just at the end of the beginning.

The follow-on research that scientists have already begun, which involves setting out the function and structure of proteins that are produced by particular genes and the biochemical pathways associated with those proteins, is going to be essential in order to develop drugs for diseases. Moreover, all this research is also going to be subject to patenting. So we may begin to see—and in fact we're beginning to see already—a repeat of the first gold rush with respect to genes and pieces of genes in the protein area and in the biochemical pathways area. This time though, the gold rush may be somewhat abated by the PTO's announcement in January that applicants must know the utility of the particular invention on which they're filing a patent.[37] And, I agree with Mr. Dickinson that the utility requirement has been raised by the PTO about as far as the Federal Circuit is going to let them raise it.

Whether the PTO has let the requirement become more liberal than the Supreme Court might think advisable given its decision-making in a case called *Brenner v. Manson*[38] back in 1966 is another question. But I think the PTO has gone about as far as it can.

Now, how concerned should we be about current or future gold rushes? Well, that brings me to the second general observation that I want to make. I don't think most of these patent applications necessarily pose a problem, particularly given that the utility requirement has been raised to the extent that the Federal Circuit will allow. As the previous speakers have mentioned, we've allowed

35. *See* Statement of Professor Rai, *infra* p. 387 (defining a single nucleotide polymorphisms as single-based variations in DNA that either may cause or may be associated with a variance of a particular disease).

36. Winston Churchill, Speech at Lord Mayor's Luncheon, London (Nov. 12, 1942), *available at* http://winstonchurchill.org/actv1942.htm.

37. *See Utility Guidelines*, *supra* note 9.

38. 383 U.S. 519, 534 (1966) (holding that an invention had to demonstrate a "specific benefit . . . in currently available form" in order to be patentable).

patents from almost time immemorial on isolated and purified forms of things that are found in nature, and that's precisely what gene patents are.

Some of the questions and the attention that gene patents get, I think, are a function of our somewhat schizophrenic attitude toward health care more generally. "Should health care be in the market or should it be out of the market?" That's a question we haven't managed to answer in our society more broadly, and certainly in the context of the gene-patenting dilemma, we're not going to answer that question. So I think, in terms of some of the political aspects, that may be what is at issue when people get concerned about patenting genes, and particularly when people get concerned about what happens if you need to have a test for a particular gene that costs too much because the gene has been patented. Well, that's a question that really concerns our health care system more broadly.

Now, biopharmaceutical research is very costly, and to the extent that patents can help companies recoup some of the cost of that research, they're helpful. In fact, they're necessary in order to get that research done. For example, a patent on a specific gene or protein that has been characterized in terms of its function may well be deserved.

What I think we need to be a little concerned about are property rights that may unduly hinder access to, what I call, basic research platforms, meaning research that enables a broad variety of further research. A famous historical example of such research was the Cohen/Boyer recombinant DNA technology, also known as the gene splicing technology. A more recent example might be raw sequence data. As Mr. Dickinson mentioned, the NIH has taken a strong position in support of having that raw sequence data be publicly available.

Finally, my third observation is that an area to watch, in terms of its importance to biopharmaceutical research and also in terms of its potential for presenting even more interesting intellectual property challenges than we've faced thus far, is the confluence of biotechnology and information technology known as bioinformatics.[39]

Let me elaborate on these points I have made to the extent I can. Where are we in terms of patenting genetic science and what comes next? Well, with respect to genes and gene fragments and other

39. *See* Statement of Prof. Rai, *infra* p. 388 (describing bioinformatics as the wave of the future in biotechnology research).

pieces of genes, biotechnology companies have already done a lot of patenting. In fact, they may have filed more patent applications on genes than there actually are genes. Recent estimates suggest that we may have about 30,000 or 40,000 genes in our body[40] down from the hundred thousand that we originally thought we might have. Well, the biotech company Incyte alone claims to have filed 50,000 patent applications on pieces of various genes so there's going to be quite a question as to the multiple applications on these various genes that exist. Thus far only about 1200 or 1300 patents on full-length genes have been granted. We'll have to see what the PTO does with tens or hundreds of thousands of gene-related applications that are still pending.

As has been mentioned and as I've discussed as well, the raising of the utility bar may doom a good number of these applications. I think that's probably a good thing. There might have been even more of a gold rush in genes and gene sequences had it not been for efforts by the NIH, and also some public and private efforts to put genetic information in the public domain specifically to create prior art so that biotechnology companies could not patent that information.

NIH has done that through its National Human Genome Research Institute project, which has made raw DNA sequence information publicly available within twenty-four hours of its being found. Perhaps even more interestingly, private companies, specifically private pharmaceutical companies, have in one particular case been interested in putting information in the public domain so that they will have access to it without the possible impediments that might be posed by patent rights in that information. The information that they have put in the public domain involves what I mentioned earlier—single nucleotide polymorphisms—or SNPs.

Now, SNPs are single-based variations in DNA that either may cause or be associated with variants of a particular disease. To the extent that one of the promises of genomics is that it will yield drugs that are precisely targeted to the particular variant of the disease that you have, pharmaceutical companies are going to need access to large amounts of SNP information. If there are lots of different claims to SNP information, we may have the problem that Mr. Dickinson alluded to of overlapping property rights to information necessary to develop a particular drug. My colleague, Rebecca Eisenberg, has

40. *See* Scott Hensley, *Proteins–Not Genes–Could Be Clue to Human Complexity*, WALL ST. J., Feb. 13, 2001, at B1.

called that the tragedy of the anti-commons.

Overlapping patent rights result in a given developer needing to license for several licenses, and the transaction costs of getting those licenses may be quite high. So perhaps, it's not surprising that these private pharmaceutical companies have banded together and spent their own money to put information in the public domain. Perhaps they're not as sanguine about the possibility of patent pools developing as some of the panelists may be today.

A challenge we are just starting to consider is the extent to which we need to put basic information about proteins in the public domain because proteins are the next area where we're seeing or beginning to see a gold rush.

Finally, there are very interesting intellectual property issues that are going to be raised by bioinformatics. Basically, bioinformatics is the wave of the future with respect to biotechnology research because it's much easier and cheaper for a pharmaceutical company, if it can, to do research on a computer than in a wet lab.

What that's inevitably going to mean is patent applications on data structures that represent proteins or DNA sequences, not just the biological version of the protein or DNA sequence. Fortunately, for purposes of those companies who would like to file these applications, the Federal Circuit's case law made it a lot easier for them in the last ten years or so.

The Federal Circuit has basically said that you can file patent applications and get patents on data structures as long as your data structure has some utility. So we should expect, and we've already begun to see patent applications on data structures such as 3D computer models of proteins. We will also see and have seen patents issued on software programs that work with these data structures to identify perhaps, with respect to particular protein, sites on the protein where a drug might attach so as to inactivate the protein.

So, those are my preliminary remarks. Let me just add that there are lots of other topics that are worth discussing. There has been a huge growth in patenting activity by universities, not just by biotech companies. This is a specific consequence of exclusive federal policy to encourage patenting by universities. But the question is whether universities should be just like any other market player.

I think that's a very fascinating question. It came up recently in the context of a stem cell patent that the University of Wisconsin holds—a very broad stem cell patent—on embryonic stem cells. So, should we have a scope of basic platform research patents be narrower than other patents?

Finally, Professor Sarnoff alluded to the question of what has all this done to the norms of science, and in particular, norms of science in university-based research where once upon a time we thought that scientists freely exchanged information with one another. What are they doing now that patenting has become the order of the day in universities?

Thank you.

DR. SPIEGEL: I'd also like to thank you all for the invite. Being last on this panel has some advantages and disadvantages. I have to make a disclaimer regarding the fact that whenever I come out to talk, I'm always warned, "Be careful, you speak for the federal government, you speak for the NIH."

Well, all of the real good issues have already been developed by Professor Sarnoff and the panel. I'd like to do a disclaimer and perhaps this allows me to just be provocative, provocative enough that perhaps the Office of General Council or the Department of Justice might not want to defend everything that I'm going to say. So, I'm not completely speaking for the federal government. And, in an audience like this, being the only person on the panel who is not an attorney, to be provocative at the end I throw myself at your mercy.

If I'm going to be provocative, why don't we begin at what the basic premise, the mission, of the patent system is. It goes back to our Constitution and its antecedents long before that. But, in Article I, Section 8, of our Constitution it says, "To promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[41] This is something that's all familiar to you.

It's the basic quid pro quo of the patent system. When you roll in all of the statutes that have been written since the Constitution, they have translated that mission into: In exchange for disclosing how to make and use your invention, your useful and novel and unobvious invention, the government will give you a monopoly, an exclusive right to exclude others from making, using, and selling your invention. This is another basic quid pro quo.

What's not to like? It's fine as long as that is a give-and-take, as long as it is a quid pro quo. Well, how would that compare to what the mission of the NIH is? Initially, it's very similar. The mission of the NIH corresponds directly to the first half of that quid pro quo.

Our [the NIH's] mission is to promote the progress of science, the biomedical sciences in particular. We are fortunate in that through

41. U.S. CONST. art. I, § 8, cl. 8.

the largess of the American people and the Congress, the resources to advance that medical science and that research is paid for. We don't need a quid pro quo in order to do that work. So, we don't have the second half- that carrot- that need for monopoly in order to provide an incentive to disclose your invention.

The second half of our mission is merely that the progress in science should be for the advancement of public health. Well, how does that mission get translated into the technologies, the inventions that come out of the NIH? Those inventions tend to fall into various categories. The broadest and most general one has to do with the fact that our scientists are coming up with basic knowledge methodologies, which they publish as true academics.

Another very broad category has to do with the more tangible types of discoveries that our scientists make that we categorize as research tools. These are, in large measure, the vast majority of the advances and discoveries that NIH scientists make and probably scientists in the biomedical area in universities make as well.

Specifically, these are your vectors, your cell lines, your knock-out mice, your antibodies. These are the tools of the trade that other scientists use in their daily research to hopefully get to discoveries and advances that move forward the public health. It's our position that these tools of the trade, which are generally already in a finished state and ready to be used, should be widely disseminated.

They are not things that in our opinion require intellectual property protection. They don't need the incentive of a right to exclude others. As a matter of fact, it's the anathema of how we feel these research tools should be used. We don't want them to be excluded from others. We want everybody to use them and use them as freely as they can.

We make other discoveries from time to time. We make discoveries of potential therapeutics, be they in the area of genomics or more traditional types of small molecules or peptide-types of molecules that have therapeutic application. Some of them are potential vaccines and some are potential diagnostics.

For these types of inventions we do the same type of basic research. We may take these through early stages of clinical trials, but lo and behold, these types of inventions will not make it beyond a few people who are human guinea pigs at clinical trials to the broader general public, which is the aim and the mission of our agency.

These types of inventions require further research and development. They require manufacturing. They require distribution. The NIH isn't in that business. I don't believe any

federal agency is in that business. For that, you require the private sector, and you require the investment of large sums of money for research and development to go through the Food and Drug Administration and through the regulatory process.

Those elements that are necessary to bring these inventions to their true fruition for the public health won't touch our therapeutics and diagnostics unless there is intellectual property protection associated with them. So, what we've created here is perhaps a dilemma, that the types of science that we are involved in, particularly the types of science that may be associated with things like the Human Genome Project and genetic sequences, are ones that would be disclosed anyway.

They would be disclosed by federal laboratories such as us, and they'd be disclosed by academics through the regular publication process. That quid pro quo of getting exclusivity for disclosure may hold for widgets or may hold for some areas in electronics but I don't think it holds in biotechnology. It certainly doesn't hold in some areas of genomics. If that's the case, perhaps we have to begin to think outside the box. Namely, that we don't have one patent system that fits all, but that perhaps for the widgets and for things where there may be true trade secrets, the patent system serves a very useful purpose.

We still need the patents for those incentives with pharmaceutical companies, but perhaps since the quid pro quo isn't quite there the way it was laid out in the Constitution, maybe we have to begin to think about new ways of creating that give and take. We have to think about areas that may put a different perspective on what it means for utility and what it means for scope, what it means for obviousness and structural relationships.

Perhaps this is a good time to leave it at that, and we can relate that to particular questions you might have.

PROF. SARNOFF: Let me do two things. I want to make a few brief comments, going down the line, and then give you each a chance to respond to each other before we take the questions.

I think that the last comments really hit the target. The question is ultimately one of the technology itself or the human motivation in regard to the technology to disclose and to invest before the disclosure. It really comes down to the question of how do you feel about monopoly or, in the case of oligopoly, the patent pools. That goes back to the basic question of what it is that you're getting a patent on. When you're talking about these basic research platforms you may feel very different about a monopoly or an oligopoly than

you would if it was not something basic.

Federal funding may make a difference. If these inventions that the federal government would fund and then disclose anyway, you would feel very different about the monopoly. You would not need it. If it is only going to happen in the private sector, maybe you would.

Then you come back down to what you are really getting a monopoly on, and, again, it is the isolated or purified forms. But, your claim's scope may be broader, because we have traditionally allowed claims to unknown embodiments with unknown utilities when you disclose one embodiment with one utility. So, you get a much broader monopoly than what you've actually disclosed.

That may be ultimately what's different in *Diamond*.[42]

E-commerce and other types of inventions are a choice, while biology is a given. You have prior users of those unknown embodiments with known utilities. That's precisely why people are resistant to making the argument that you shouldn't be able to patent my body. In actuality, you are not talking about patenting your body, rather, you are talking about patenting a purified sequence but then getting a patent on a broader use of that purified sequence, which people may already be using.

Let's take this down the line.

MR. DICKINSON: Thank you again. Dr. Spiegel and I are on panels on a lot of occasions so we're used to this debate and dialog. So, let me respond in some of my traditional ways.

The question that arises is why do we need this incentive in the biotechnology area? Does it actually exist? Let me suggest one answer to that question. When the Human Genome Project was first proposed, it was due to finish in about 2005, according to budget. Then, a gentleman named Craig Vedder left the Human Genome Project, founded a company in Maryland called Celera, and announced that he was going to do it with sequences he's acquired from the company. The next thing you know, the budget's upped and we're standing in the White House in the year 2000 announcing the fact that the Human Genome Project is now complete. I'd suggest a key reason why that happened was the fear on the part of the managers of the Human Genome Project that the patent system would indeed impact their work and that they felt they needed to accelerate the process. So I would suggest the patent system worked exactly as it should have in terms of providing an incentive for that research to be done and to be done more quickly, presumably to the

42. 447 U.S. 303 (1980).

betterment of everyone.

Secondly, the suggestion that NIH and the fundees of NIH don't need the incentive of the patent system may be belied somewhat by the fact that the NIH is one of the larger filers of patent applications in the federal government. As I mentioned before, they obtain many patents on gene sequences outside of the human gene sequence. That would suggest, I think, that there are a number of reasons why one would want to get patents in addition to the incentive reason.

It may be the law of unintended consequences comes in here a little bit but I don't fault the NIH and Dr. Varmis and others from making the decision to dedicate the human gene patents that they discovered to the public. I think that's a very noble thing to have done, and it's certainly a conscious and valuable decision to have been made. One question that it gives rise to, though, is that they then give up control of that because there certainly, I assume, will be instances when pharmaceutical companies and diagnostic manufacturers will come along in later years, discover new, very important, and lifesaving uses for those gene sequences or employing those gene sequences. They will develop a pharmaceutical, get a patent on a method of use, get a patent on the pharmaceutical itself, or a method of using the diagnostic, and then they can charge whatever the market will allow. If the federal government had maintained and gotten the patent on that gene sequence and then the pharmaceutical company was required to obtain a license from the federal government, the pricing policy might have been somewhat different.

With regard to the research tool exemption, we have this debate a lot. If the research tools are being used by pure academics for academic research, even if they're technically infringing, the reality is nobody is going to sue a pure academic researcher. There's no upside to it. Why would a commercial entity want to risk the negative public relations impact of suing some poor researcher who is just researching in his lab?

The problem is where do you draw that line? There have been several attempts to write statutes that would create a research tool exemption, and the question is where along that spectrum from pure academic research to pure commercialized research does that line get drawn?

Now, as Jack [Speigel] suggested, a lot of the reason that federal dollars are put into NIH research is not so that scientists can write papers and improve their standing among their colleagues. No. The dollars are spent to improve the betterment of the United States and

presumably the world's peoples. That requires that those discoveries be commercialized. So, those research tools will almost inevitably lead to commercial activity.

Secondly, research tools are a big business in the United States. NIH has concerns about obtaining a license for research tools on inventions they can make. They don't ask for discounts off of centrifuge manufacturers that have patented technology or test tube manufacturers that have patented technology because a patent happens to exist or a research tool exists with regard to that.

What's interesting about this area is that in a lot of intellectual property questions there is very much of a two-sided coin nature to it. Where you stand is where you sit. The questions, provocative and interesting as they are, are never simple. I think that's where I'll end.

MR. KILYK: I'd like to just point out two things. One, when a company, an organization, someone like the NIH decides to, in effect, dedicate to the public the knowledge it's acquired on something, like the sequences that have been laid out in the Human Genome Project, the reason it works and that more development can take place and the benefits of that development can be made available to all of us is generally because of the patent system.

It's a situation where the government may give up its rights on something like the basic gene sequences. But, one of the things that's very clear from where I sit is that I can't think of a single client that I've ever worked with that would pick up one of those gene sequences and spend the required 50, 100, 150 million dollars that it will take to determine whether that gene sequence can be used to treat a certain disease and be brought to the market place without a patent being in that mix someplace. So the only reason that it works with regard to the Human Genome Project is because clients are coming to firms like our own and saying, okay, there are no patent rights on the gene. Therefore, if I develop something with the gene, is there some other type of patent right I can get—for example, on the method of use, or on the overall pharmaceutical composition—so that if it does pan out, I can get a return on my hundred million dollar investment. Otherwise, I'll have gone through all this trouble, gotten FDA approval, and the very next day someone will be able to file an ANDA application with the FDA and put out a generic equivalent and undercut my price. I'll never get the investment back, not just on that product, but probably the even nine out of ten other products that never even made it that far because they failed, but for which similar sums of money may have been expended.

So, the patents are still important. It's just that in that one

particular aspect, it's at a low enough level that there's room to acquire patents on the use or the composition so that some protection can still be acquired to get that return on investment later on. If that weren't the case, all that knowledge would be sitting on the side. Maybe you'd have some grad students and some universities looking at it, but you're not going to have the venture capitalists looking at it. You're not going to have the big pharmaceutical companies looking at it.

In effect, that knowledge is going to be wasted unless the government then wants to move in and pick up the ball and finish off doing that clinical work, which, as Jack Spiegel has alluded to, currently we're not set up to do. And that's another political question—whether the United States wants something like that or not.

The other point is with respect to something that Josh Sarnoff mentioned—should the patent laws be allowed to prevent you from doing things with your own material that had been done before? With all due respect, that's not quite right. If it had been something that had been done before, he wouldn't have been able to get a patent on it in the first place.

By definition, you are patenting something that is new and unobvious and useful. Those are the requirements, so it's something that didn't happen before, either inherently, accidentally, or in nature. So now, all you're preventing someone from doing is something that's brand new that presumably benefits society and for which someone is going to get, obviously, a return on some investment or they wouldn't have gone through the patent process in the first place.

So, you're no worse off than if that work had never been done. But now that it has been done, don't you want that disclosed in the public? Don't we all want the benefit of that? And the way we're going to get that benefit and that disclosure so that we can build on it to make even better discoveries is to offer the discoverer of that information some quid pro quo. And that's the patent system.

PROF. RAI: I think that a lot of the disputes that we're having on this panel can be boiled down to two issues. One is a question of timing. If you think of R&D somewhat simplistically as a linear process from upstream research to downstream product—even though it always has nonlinear aspects to it—the question is where should the patent kick in during the process? I think that's a very difficult question to answer in any given case, but that's what we're struggling toward in this debate that we're having about patents.

One point that I thought Mr. Kilyk made that was very interesting was that some of his clients are still willing to do research on some of this stuff that's out there in the public domain because they think that they can get some additional patents along the way down to the downstream product.

Well, why isn't that a good thing? The raw information is out there in the public domain for everyone to use, and if you can add value to that raw information along the way, you get a monopoly right on that added value. So, once again, where in the process from upstream research to downstream product should monopoly rights kick in? Granted that's a very, very difficult question to answer, but there is no reason to believe that monopoly rights need to kick in at the most upstream piece of the research that's done. That strikes me as a dubious proposition at best. And it seems to me that a lot of what the NIH has been doing—and I really do applaud their efforts—has been trying to figure out whether patent rights in particular areas need to kick in at the most upstream level.

Okay, so that's one question. The other question is what institution should determine when the patent rights kick in? One mechanism for determining when patent rights kick in would be to modify the patent statute in some way. The problem is I don't trust Congress to do that.

I have no idea how Congress would modify the patent statute to determine where patent rights should kick in. To some extent, the utility requirement does it, but it's a very, very gross mechanism for doing so. It's blunt and it doesn't particularly work well because courts have to apply it, and courts don't know much about scientific research in the first instance. Therefore, I would be very wary about modifying the patent statute or setting up mechanisms for subpatentable invention because, again, Congress and the courts are probably not the best institutions for this kind of thing.

I do think that the NIH can play a really valuable role in this regard. The NIH is an institution that obviously is very steeped in research, knows the research issues extremely well, and hands out a huge amount of money to people to do research. So, it can tell universities that in certain instances they shouldn't seek patent rights on the most upstream research.

Unfortunately, it can't do this as much as it probably should be able to do because of certain language in the Bayh-Dole Act,[43] which I

43. Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200-211 (2001)). Section 202(a) of the Bayh-Dole Act states that grantees of federal funding may "elect to retain title to any subject invention" and that a funding

believe should probably be amended slightly. In any event, it has managed to do so effectively, even without explicit legal authority to do so, through informal mechanisms in the context of the Human Genome Project, in the context of SNPs, and in the context, to some extent, of ESTs.

So, I guess I'm setting up our final panelist. I really do think the NIH has a huge role to play here, particularly because, with respect to the research that NIH funds, if they decide that we shouldn't have patents on the most upstream research that they are funding. With respect to that research, you don't need the incentive to create that research in the first instance, as Dr. Spiegel has suggested already, because there's public funding.

So, I think that we need to think creatively about how publicly funded research might differ from privately funded research with respect to some of the relevant patenting issues.

DR. SPIEGEL: Well, as before, all of the good tidbits have already been disclosed by my colleagues. I hope you didn't take away from anything I said the notion that the patent system is bad. I think, as I alluded to, without the incentives of patents some of our most important discoveries that we make wouldn't make it to the pharmacy.

You don't go down the road to the CVS and ask if you have the latest NIH knock-out mouse. You're interested in the therapeutic drugs that come out of our laboratories, and we need a patent system to provide incentives for private industry to be involved in developing those drugs and bringing them to market.

I do see a distinction sometimes when the early stage discoveries are extremely basic and affect overall research areas such as the Human Genome Project did. I don't think you want to be in a situation where by virtue of mere sequencing, something is coming out of a machine where you have very little idea of what the ultimate use of that piece or even of a larger section of sequence is. This is really involved with being able to get a product patent, which will later on allow you to dominate all aspects, all areas that that gene or that sequence may be involved in.

There may be nothing wrong with not giving a patent on the product but being able to get patents on the individual different uses that you find for that patent. The scope of those individual use patents will be commensurate with what you discovered. Indeed,

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agreement may provide otherwise only in "exceptional circumstances when it is determined that restriction or elimination of the right . . . will better promote the policy and objectives of that chapter."

what you tend to find is that many of these biotechnology products have multiple uses, many of which are not contemplated early on. And, our patent system permits product patents to dominate all the future use patents.

I think that's a problem. I think that's an issue. In some cases, that's good. I mean, if you're the holder of that patent you've got something that's much more valuable. From our perspective, that is something to be at least concerned about. Again, from the other perspective of the research tools, where you stand on this issue depends on where you sit.

But I don't care where you sit. We make a lot of money off of our research tools in private industry. We license them out without intellectual property rights as commodities. We sell them the same way you'd buy a hammer or buy a saw to build your house. Or, no matter how you feel about Microsoft, you buy their word processing. And how would you feel if a percentage of whatever you wrote for the word processing [was owed to Microsoft], or a percentage of your house was owed to every hammer, every saw, and every nail? The basis for intellectual property protection is to exclude others.

And it's true. I think you're not going to find too many companies in private industry who are going to step into a university researcher's lab and say, "stop doing that research using my tool." But what they will say is, "You need to take a license. You're infringing my patent." We won't stop you from doing the research, but anything that comes out of that research belongs to us, or a royalty on it belongs to us.

It's what we refer to as "reach-through," and we have a problem with reach-through types of licensing. As a matter of principle, I think that being leveraged to be able to force reach-through licensing can be eliminated, at least at the intellectual property level, by convincing people that they don't necessarily need intellectual property protection on those types of research tools.

PROF. SARNOFF: We are out of time so we're going to have to avoid questions. I'm going to say something very briefly and then turn it over for the last word to Commissioner Dickinson.

The point just made I think highlights the point I was trying to make, which is that the scope of the claim goes to undisclosed embodiments with undisclosed uses. The question therefore is, whether the scope of claiming is too broad for what has been the incentive to disclose in the first place. The incentive is still necessary, but it is the scope of the claim that's really at issue.

MR. DICKINSON: Two points on what Dr. Spiegel said. I would agree with him certainly on the last point. I think what the terms of a

license are and the ability of the parties to negotiate those terms is really one of the most important and critical aspects of how this all plays out. I think the NIH plays and has played a similar role. The best example is an example that Professor Rai alluded to a little while ago and that's the very broad patent the Wisconsin Alumni Research Foundation (WARF) has on stem cells.

NIH was in a position to negotiate how that license would play out and had as part of their negotiating position the fact that the President of the United States was interested in the issue. It was able to drive a good bargain with WARF so that WARF would not have reach-through rights, and I think that's negotiated, negotiated at arm's length, and exactly as the market would have it.

To the point about utility and how the invention is arrived at, just as a legal matter, that has to be positioned against the fact that in Section 103, Congress has inserted a sentence that says, how the invention is arrived at is irrelevant and should be irrelevant to whether something is patented or not.[44]

It does not matter whether you spend thirty years in a lab slaving over the invention and finally arrive at it, or as, a good example, Kary Mullis, the Nobel prize winner for polymerase chain reaction, driving up the coast of California one day in Mendocino suddenly comes to him the idea of polymerase chain reaction, he pulls over and writes it on the back of a McDonald's napkin and then drives on his way home. The fact that the scientists employ million-dollar sequencers to come up with inventions, at least under the patent law, does not implicate whether something should be patentable or not because the law says, how you arrive at that invention is irrelevant.[45]

MR. SARNOFF: Why don't we thank our panel. That was tremendous. We can take a break and reconvene at a quarter to the next hour.

(WHEREUPON, A RECESS WAS TAKEN)

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44. 35 U.S.C. § 103 ("Patentability shall not be negated by the manner in which the invention was made.").

45. *Id.*